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AUG 1 4 2000

APPENDIX A 510(K) SUMMARY

Baby Dopplex® 4000

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USA
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Name of Device: **Baby Dopplex® 4000 (BD4000)**

Manufactured by: Huntleigh Diagnostics Ltd
35, Portmanmoor Road,
Cardiff
South Glamorgan CF24 5HN
Wales, U.K.

Contact Person at Manufacturing Facility:

B.J.Colleypriest
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Date Special 510(k) prepared: **22 May 2000**

Classification Name

Fetal Ultrasonic Monitor and Accessories (21 CFR § 884.2660)

Predicate Devices

Baby Dopplex 3000 (ABD3000) K963711.

Hewlett Packard GmbH's Series 50 range of Fetal Monitors Model N°s M1351A & M1353A (K921957 & K921956 respectively).

Device Description

The BD4000 is a fetal monitor, which produces cardiotocographs (CTG) and gives indication of uterine activity by processing received ultrasound/electrical signals. In basic format, the device performs antepartum fetal monitoring and uterine activity functions. Connecting separate modules to the BD4000 main unit allows it to perform Intrapartum monitoring operations.

In instances of twin presentations, two Baby Dopplex® 4000 units can be linked together so that both fetuses can be monitored simultaneously.

Fetal movement detection is also monitored by processing the received Doppler signals.

The complete BD4000 system has been tested to ensure compliance with internationally recognised medical electrical equipment standards. Tests have been performed in accordance with the requirements of IEC601-1, BS EN60601-1, UL2601-1, BS EN 60601-1-2, BS EN55011 & DIN VDE 0750-1. A checklist of Essential Requirements tests has been compiled in accordance with the direction of the Medical Devices Directive 93/42/EEC. Biocompatability has been assessed in line with the principles contained within BS EN30993-1.

Intended use

The BD4000 device performs the same functions as the Hewlett Packard predicate devices. The BD4000 can also monitor twins by linking two unmodified devices together.

The BD4000 is also an upgrade of the predicate ABD3000 (K963711), and includes intrapartum and twins monitoring functions that were not available on the previous model.

The fetal parameters are displayed in the same way as those of the predicate devices.

The following table briefly compares the monitoring characteristics of the applicant device to its predicate devices.

Monitoring Mode	Baby Dopplex® 4000	Baby Dopplex® 3000 (K963711)	Hewlett Packard M1351A (K921957)	Hewlett Packard M1353A (K921956)
Monitoring fetal hea rate using ultrasoun	Yes	Yes	Yes	Yes
Detect fetal movement	Yes	No	Yes[(1)]	Yes[(1)]
Monitoring twin feta heart rate using ultrasound	Yes[(1)]	No	Yes[(1)]	No
Monitor fetal heart rate using FECG	Yes[(1)]	No	Yes	Yes

NB: [(1)] optional feature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2000

Mr. Bryn J. Colleypriest
Technical Co-ordinator
Huntleigh Diagnostics Ltd.
35 Portmanmoor Road
Cardiff
CF24 5HN
UNITED KINGDOM

Re: K001677
Baby Dopplex® 4000
Dated: July 21, 2000
Received: July 26, 2000
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Mr. Colleypriest:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

APPENDIX C INDICATIONS FOR USE

510(k) Number K001677

Device Name: **Baby Dopplex® 4000**

Indications for Use

The Baby Dopplex® 4000 is a fetal monitor, which produces CTG's and gives indication of uterine activity by processing received ultrasound/electrical signals.

In basic format, the device performs antepartum fetal monitoring and uterine activity functions.

Connecting separate modules to the Baby Dopplex® 4000 main unit allows it to perform Intrapartum monitoring operations.

In instances of twin presentations, two basic Baby Dopplex® 4000 units can be linked together so that both fetuses can be monitored simultaneously.

Fetal movement detection is also monitored by processing the received Doppler signals.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001677

Prescription Use ✓ OR Over the counter use _____
(Per 21 CFR 801.109)